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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/297,652	07/08/99	THOMAS R	MIJ-00105

HM22/0509

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EXAMINER
BADIO, B

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 05/09/01

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/297,652

Applicant(s)  
Thomas

Examiner  
Barbara Badio

Art Unit  
1616



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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**Final Office Action on the Merits**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Objections***

2. The objection of claims 36 and 37 under 37 CFR 1.75(c), as being of improper dependent form is withdrawn.

***Claim Rejections - 35 USC § 102***

3. The rejections of claims 1-5, 7-8, 11-15, 18, 21, 22, 27 and 29-37 under 35 USC 102(b)/(e) over Papandrea (AU-34351/89 or US 5,527,779) are maintained.

Applicant argues that the pending claims are drawn to therapeutic methods and pharmaceutical compositions containing one or more corticosteroids which are selected to interact with a gold compound such that the corticosteroid provides a particular therapeutic effect, namely a preferential synergistic action against an inflammatory and/or a proliferative disorder, or equal action toward each of these disorder components. The cited prior art, according to applicant, does not teach or suggest the selection of any corticosteroid based on such effects much less corticosteroids other

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than betamethasone dipropionate. Applicant's argument was considered but not persuasive for the following reasons.

The cited prior art teach a synergistic effect of the mixture of gold compounds and corticosteroids in treatment of inflammation such as psoriasis. The ordinary artisan in the art at the time of the present application would know that psoriasis has both an inflammatory as well as a proliferative component. The ordinary artisan would have the reasonable expectation that the synergistic action of the combination as taught by the prior art would be against these components of the inflammatory condition, psoriasis. The fact that the references are silent as to the action of corticosteroid in the mixture is irrelevant because said action is present because the action of the compound and the compound are not separable. In addition, selection of corticosteroids having greater synergistic effect against any of the components of psoriasis when combined with a gold compound require only routine experimentation and such is within the level of skill of the ordinary artisan in the art.

Applicant also argues that the only combination taught by the references is based on the use of betamethasone dipropionate. It is noted that the claimed mixture contains a corticosteroid, such as betamethasone dipropionate and a gold compound. The references teach the use of any corticosteroid, preferably betamethasone dipropionate and any gold compound such as auranofin, aurothiomalate and aurothioglucose. The references also teach that substitution of any gold compound

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taught by the reference in the exemplified compositions would be effective. Thus, the combination of aurothiomalate or aurothioglucose or any of the other gold compounds taught by the reference with any corticosteroid including betamethasone dipropionate would readily be envisaged by the ordinary artisan.

For these reasons and those given in Paper No. 9, the rejection of claims 1-5, 7-8, 11-15, 18, 21, 22, 27 and 29-37 under 35 USC 102(b)/(e) over Papandrea (AU-34351/89 or US 5,527,779) are maintained.

***Claim Rejections - 35 USC § 103***

**4. The rejection of claims 1-37 under 35 USC 103(a) over Papandrea (AU-34351/89 or US 5,527,779) is maintained.**

Applicant's argument and the examiner's response as they relate to Papandrea are as discussed above in #3.

Applicant also argues that DeLong et al., Weyburn-Mason and Wolf like Papandrea fail to teach or suggest the differential synergistic interaction between gold compounds and corticosteroids. Applicant also argues that the methods taught by DeLong et al., Weyburn-Mason and Wolf for treating psoriasis and rheumatoid arthritis do not include the use of either a corticosteroid or a gold compound and that the references teach away from the claimed invention because they teach effective alternative methods and compounds for treating these diseases.

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In response to applicant's argument against DeLong et al., Weyburn-Mason and Wolf, it is noted that these references were used to show that the use of gold compounds or corticosteroids in treating these diseases are known in the art. As stated in the previous Office Action, the court has held that combination of two or more compositions/compounds taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose is not patentable because said would be obvious to one having ordinary skill in the art. The fact that the references do not themselves use the compounds of the claimed invention in treating the diseases is not relevant because they show that the use of each of the components of the claimed invention would have been known in the art for treating the diseases at the time of the present invention and, thus, the combination is prima facie obvious. The teaching of the references of alternative methods and compounds for treating the same diseases is not a teaching away from the claimed invention. Again, the examiner notes that said composition would be obvious to the skilled artisan in the art at the time of the present invention.

For these reasons and those given in Paper No. 9, the rejection of claims 1-37 under 35 USC 103(a) over Papandrea (AU-34351/89 or US 5,527,779) is maintained.

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***Conclusion***

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

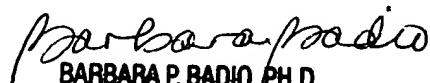
***Telephone Inquiry Contacts***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara Badio whose telephone number is (703) 308-4595. The examiner can normally be reached between 7:30 am and 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

May 8, 2001

  
BARBARA P. BADIO, PH.D  
PRIMARY EXAMINER